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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/372,036 08/11/99 SCHUBERT

F MERCK1694D2

EXAMINER

023599 HM12/0309
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SUITE 1400
ARLINGTON VA 22201

BASKAR, P
ART UNIT

PAPER NUMBER

1645
DATE MAILED:

03/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/372,036

Applicant(s)

SCHUBERT PETER ET AL

Examiner

Padma Baskar

Group Art Unit

1645



☒ Responsive to communication(s) filed on Jan 23, 2001

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 39-58 is/are pending in the application.

Of the above, claim(s) 39-41 and 44-49 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 42, 43, and 50-58 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 39-58 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. Applicants response to restriction requirement and amendment filed on 1/23/01 is acknowledged. Claims 3-10 and 15-38 have been canceled. New claims 39-58 have been added. Claims 39-58 are pending in the application. Claims 42-43 and 50-58 are currently under examination.

Priority

2. This application claims foreign priority under 35 U.S.C. 119(a)-(d) to Fed Rep Germany 4219111.4, filed on 6/11/1992 and Fed Rep Germany 42395671.4, filed on 11/25/1992. However, the priority documents are in German. English translated certified copies are required in order to obtain foreign priority.

This application is a division of 08/456,670 filed on 6/1/1995, Patent 5,932,415 which claims foreign priority to applications Fed Rep Germany 4219111.4, filed on 6/11/1992 and Fed Rep Germany 42395671.4, filed on 11/25/1992. However, US application 08/456,670 is filed more than two years after obtaining foreign priority. It is not clear to the examiner where is the continuation between foreign priority and US Application ? Clarification is required.

Oath/Declaration

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Applicant has failed to check the box on page 1 of the Declaration indicating that a copy of the specification is attached hereto.

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Drawings

4. The drawings are objected to by the draftsman under 37 C.F.R. 1.84 or 1.152. See PTO-948 for details. Correction of the noted defects can be deferred until the application is allowed by the examiner.

Election/Restriction

5. Applicant's election with traverse of Group IV, claims 42-43 and 50-58 in Paper No 7. is acknowledged. The traversal is on the ground(s) that the restriction to separate six inventions produces an undue burden on applicants to file, prosecute and pay maintenance fee. And also Groups III, V and VI should be examined together because a proper search for the claims of Groups III, V and VI would overlap with a search of claims of Group IV. And Group I and II should be examined together because a proper search for the claims of Group I would overlap with a search of claims of Group II. This is not found persuasive because of the following reasons. Regarding applicants comments on page 1 of the response, the M.P.E.P 803 states that : "for purposes of the initial requirement, a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search". Examiner has clearly shown in the previous office action that Groups I, II, III, V and VI acquire separate status in the art and search is different for different inventions. Regarding rejoining the Groups III, V and VI, no allowable claims are presently contained in the instant application.

The requirement is still deemed proper and is therefore made FINAL.

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6. Claims 39-41 and 44-49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, the requirement having been traversed in Paper No. 7.

Claim Rejections - 35 USC § 112

7. It is apparent that in claims 42-43 and 50-58 antibodies are required to practice the claimed invention. As required elements, they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If they are not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the pertinent cell lines / hybridomas which produce these antibodies. See 37 CFR 1.801-1.809.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

NOTE THE CURRENT ATCC DEPOSITORY ADDRESS

American Type Culture Collection, 10801 University Boulevard, Manassas, VA 20110-2209

Applicant is reminded that the following and should amend the specification accordingly.

The current address of the ATCC is as follows:

American Type Culture Collection, 10801 University Boulevard, Manassas, VA 20110-2209

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If the original deposit is made after the effective filing date of an application for patent, the applicant should promptly submit a verified statement from a person in a position to corroborate the fact, and should state, that the biological material which is deposited is a biological material specifically identified in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which case the statement need not be verified. See MPEP 1.804(b).

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 42-43 and 50-58 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants have not demonstrated that the instant peptides can be used to generate antisera which recognize p60. Furthermore, applicants have provided no evidence of the specificity/sensitivity of these antibodies which specifically binds to the p60 protein from pathogenic *Listeria*. In the absence of such evidence, a routineer would have no reasons to assume the instant antibodies had the claimed specificity/sensitivity. Applicant discloses on page 11 of the specification, lines 5-10, that a particular peptide derived from p60 will not generate an antisera which recognizes p60. This confirms the art recognized notion that peptides derived from a

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particular protein will not a priori be useful in the generation of antisera which recognizes the intact molecule.

Examples 13 and 14 (specification 20-21) teach that the bacterial cultures were used to identify the antibodies raised against peptide SEQ.ID.NO 42 by immunological methods such as dot blot and immunoblotting but there was no guidance how these antibodies are screened to show that they bind to p60 protein. Applicants have provided no guidance as to how monoclonal antibodies which are specific for pathogenic p60 protein bind to epitopes from the peptide, SEQ.ID.NO 17, 20, 26, 29, 30 or 31. Furthermore, Applicants have not provided guidance how these antibodies are screened for after the fusion procedure disclosed in Example 10 of the specification. Therefore, the specification is not enabling for the instant invention.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 43, 54-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of a process whereby said antibody is made in product claim 42 carries no patentable weight in this product claims.

State of the Art

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Kohler et al (Infection Immunity 1990, 58, 1943-1950) in view of Lerner (Adv in Immunol, 1984, 36, 1-44). Kohler et al teach that the entire p60 protein derived from Listeria and there are

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regions of the p60 molecule which are shared among Listerias that are both pathogenic and non pathogenic and there are regions of the p60 that are specific for pathogenic Listerias such as L.monocytogenes. The prior art teaches making antibodies to p60. Lerner teaches that peptides derived from whole sequence of the whole protein can be used to produce antibodies that recognize the entire protein.

Alstyne et al 1996, US. Patent No: 5,510,264 and 5,556,757 disclose monoclonal antibodies that bind to p60 protein of L.monocytogenes.

Status of Claims

13 No claims are allowed.

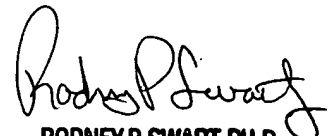
14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

2/27/01


RODNEY P. SWART, PH.D
PRIMARY EXAMINER